Preferred Drug List Committee Meeting

Meeting Minutes, Open Session
June 12, 2019 11:30 a.m. to 1:00 p.m.
DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Jessica Bates, Pharm.D., BCPS (Chair)
Emily Blew, Pharm.D.
Katherine Grimsley, M.D.
Megan Hedden, Pharm.D.
William Pankey, M.D
James Rider, D.O.
Donna Sweet, M.D. (Phone)
Wayne Wallace, M.D.

Board Members Absent:

Taylor Gill, Pharm.D., BCPS
Robert Haneke, Pharm.D.

KDHE-DHCF/Contractor Staff Present:

Victor Nguyen, Pharm.D.
Margaret O'Donnell, Transcriptionist

KDHE-DHCF Staff Absent:

Annette Grant, RPh.

DXC/HID Staff Present:

Karen Kluczykowski, RPh.
Kathy Kaesewurm, R.N., BSN

MCOs Present:

Angie Zhou, Pharm.D. – Sunflower Health Plan
Alan Carter, Pharm.D. – Aetna Better Health of Kansas
Jeanne Cavanaugh, Pharm.D. – UnitedHealthcare

Public Attendees:

Jim Baumann, Phil King, Pfizer; Rick Kegler, Otsuka; Julie Long, Raquel Jordan, Kirsten Mar, AstraZeneca; Maggie Murphy, Teva; Marla Wiedenmann, NNI; Erin Hohman, Janssen; Donna Osterland, Genzyme; Sam Hausmann, KU Pharmacy; Garth Wright, Genentech; Laura Hill, AbbVie, Meghan Kerrigan, Merck; Brent Young, GBT; Nick Boyer, Xeris; Kaylee Croft, Dawn Lease, Bernard Koop. Illegible names not included.

Item	Notes
I. Call to Order	Dr. Bates called the June 12, 2019 PDL Committee meeting to order at 11:33 a.m. Dr. Bates requested introductions from all those present at the table and notified the public attendees about the rules of public comment. She also requested that if anyone wishes to make a public comment, they must fill out and turn in to her the Conflict of Interest Form prior to speaking.
II. Review and Approval of March 13, 2019 Meeting Minutes.	The draft minutes from the March 13, 2019 meeting were reviewed. Dr. Wallace moved to approve the minutes. Dr. Grimsley seconded the motion. The motion carried unanimously, and the minutes were approved.
III. Old Business **A. Consent Agenda Items** **i. PDL New Drug Placements** 1. Actemra® ACTpen™ 2. Adhansia XR™ 3. Jatenzo® 4. Lexette™ Foam 5. Lotemax® SM 6. Proair® Digihaler™ 7. Promacta® Powder Packets 8. Qmiiz ODT 9. Tosymra™ 10. Tresiba® Vial	**Background:** At the September 13, 2017 PDL meeting, the Committee agreed to the "Consent Agenda Items" pre-management process and to place the associated drug list under the Old Business section. **Public Comment:** None. **Board Discussion:** Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.

Item	Notes
IV. New Business **A. Acne Agents (Topical) – Request to Divide this PDL class into Acne Agents (Topical) - Subclasses**	**Background:** The Acne Agents – Topical PDL class was first introduced to the PDL committee as a new class in May 2015 and was most recently reviewed in September 2018 with the addition of Altreno™. Given the continual addition of acne agents to the market, the proposal today is for the approval for this class to be divided into subclasses of topical acne agents. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve. Dr. Blew seconded the motion. The motion carried unanimously.
B. Immunomodulation Agents for Adult Rheumatoid Arthritis, Ankylosing Spondylitis, Crohn's Disease, Plaque Psoriasis, Psoriatic Arthritis, Ulcerative Colitis – Addition of Biosimilars for Remicade® (Renflexis®, Inflectra®, Ixifi™)	**Background:** The Immunomodulation Agents were first approved for addition to the PDL, under the title of Biologics, in December 2009. There are six Immunomodulation Agents Disease State PDL classes that include the biologic reference drug, Remicade®. Renflexis®, Inflectra®, and Ixifi™ are approved as biosimilars to Remicade®. According to the FDA, biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. **Public Comment:** Jim Baumann with Pfizer spoke on behalf of Inflectra®. Meghan Kerrigan with Merck spoke on behalf of Renflexis ® and informed the committee that it is currently patent-protected by Remicade® so the pediatric ulcerative colitis indication is not in the Renflexis® label or the other biosimilar agents.

Item	Notes
B. Immunomodulation Agents for Adult Rheumatoid Arthritis, Ankylosing Spondylitis, Crohn's Disease, Plaque Psoriasis, Psoriatic Arthritis, Ulcerative Colitis – Addition of Biosimilars for Remicade® (Renflexis®, Inflectra®, Ixifi™) (Continued)	Erin Hohman with Janssen spoke on behalf of Remicade® and that GI experts don't always recommend switching these products. No biosimilar has been approved as interchangeable by the FDA. **Committee Discussion:** Dr. Wallace moved to approve. Dr. Blew seconded the motion. The motion carried unanimously.
IV. New Business **C. Immunomodulation Agents – Asthma - New Class -Cinqair®, Dupixent®, Fasenra™, Nucala®, Xolair®)**	**Background:** Immunomodulation Agents for Asthma as a PDL class is being presented today for approval. All five immunomodulation agents listed are FDA approved for moderate to severe asthma. The increase in numbers of immunomodulation agents approved and available for use for patients with asthma, allows for the opportunity to manage cost containment by use of the PDL. The State has been managing immunomodulation agents by indication on the PDL since December 2009. **Public Comment:** Julie Long with AstraZeneca spoke on behalf of Fasenra™. Maggie Murphy with Teva spoke on behalf of Cinquair®. **Committee Discussion:** Dr. Wallace moved to approve. Dr. Pankey seconded the motion. The motion carried unanimously.

Item	Notes
D. Overview of the PDL Program	**Presentation by KDHE:** General program information was presented to the PDL Committee for the benefit of the new PDL Committee members. Legislative origin, Non-preferred PDL PA criteria, Consent Agenda Item Process, and a visual of the Kansas Medicaid PDL were presented. **Committee Discussion:** There were questions about what the state considers when managing the PDL, why some formulations of the same drug are preferred and some are non-preferred, the 90-day maintenance drug list, and nebulized medications, drugs on the Beers list, coverage on the medical and pharmacy side for physician administered drugs that can be self-administered. The state responded that the many factors are taken into consideration when determining preferred and non-preferred PDL status, the FDA does not consider different formulations to be interchangeable, the state has been working to improve their PA program, the 90-day maintenance drug edit only hits after three fills of 30-day supply have been filled, and that the nebulized formulations will be re-considered, the Beers list is something for future consideration, and other clinical PA questions will be considered in the future or will be addressed in the Clinical PA program.
E. New PDL Committee Chairperson	**A motion and a second was made for Dr. Bates to be the new PDL Committee Chairperson.** **Committee Discussion:** Dr. Wallace moved to approve. Dr. Hedden seconded the motion. The motion carried unanimously.
F. New PDL Committee Interim Chairperson	**A motion and a second was made for Dr. Hedden to be the new PDL Committee Interim Chairperson.** **Committee Discussion:** Dr. Bates moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.

Item	Notes
V. Open Public Comment	Jim Baumann with Pfizer welcomed the new PDL Committee members and encouraged the Committee to recommend to the State when they feel strongly that an agent should be PDL-preferred.
VI. Adjourn	Dr. Wallace moved to adjourn. Dr. Blew seconded the motion. Dr. Bates adjourned the meeting at 12:32 p.m.

June 2019 Consent Agenda Item List

This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board. The Extended Consent Agenda was approved at the March 2019 PDL Committee meeting and the April 2019 DUR Board meeting.

Drug Proposed - Consent Agenda Item	Compare Drug	Supporting information	Meeting Date listed on the PDL Agenda	PDL Committee Approval Yes/No
Actemra® ACTpen™	Actemra Vial		6/12/2019	
Adhansia XR™*		Other agents -ADHD -Methylphenidate Type Agents	6/12/2019	
Jatenzo®*		Other Testosterone agents-Adrogenic Agents Class	6/12/2019	
Lexette™ Foam		Other Halobetasol Propionate agents Corticosteroids - Topical - High Potency	6/12/2019	
Lotemax® SM	Lotemax® Gel 0.5%		6/12/2019	
Proair® Digihaler™	Proair HFA		6/12/2019	
Promacta® Powder Packets	Promacta® Tablet		6/12/2019	
Qmiiz ODT	Mobic		6/12/2019	
Tosymra™		Other Sumatriptans - Triptan Agents	6/12/2019	
Tresiba® Vial	Tresiba® Flexpen		6/12/2019	
*Waiting for rebate labeler status.				